

## Fertility Centers of Illinois COVID-19 Vaccine FAQ April 25, 2021

*These questions have been updated from the American Society for Reproductive Medicine guidelines published April 21, 2021 and additional research.*

As we have crossed the boundary of 500,000 US deaths from the COVID-19 virus, the physicians of Fertility Centers of Illinois have taken pause to reflect on the effects of the pandemic in the US and in our own community. As health advocates for our patients, we seek to provide the latest knowledge to support your health and your decisions.

The physicians of FCI agree with American Society for Reproductive Medicine (ASRM) that **“everyone, including pregnant women and those seeking to become pregnant, should get a COVID-19 vaccine. The vaccines are safe and effective.”** The Center for Disease Control research indicates that Pfizer and Moderna’s SARS-COV-2 vaccines are safe for pregnant women, and they have recommended priority groups for vaccine distribution include pregnant people.

Because all three COVID-19 vaccines, including mRNA and adenovirus vector types are not composed of live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies, but studies still need to be done to assure there are no risks to pregnancy from the vaccines. FCI will not be administering COVID-19 vaccines.

We strongly encourage women to educate yourself with validated information, such as [COVID-19 Vaccines and Pregnancy \(ACOG\)](#) to learn about the American College of Obstetricians and Gynecologists' views on the COVID-19 vaccine with pregnancy and American Society of Reproductive Medicine recent statement, [COVID-19 Vaccine Guidelines/Recommendations \(ASRM\)](#).

The physicians of FCI also support the statements of the Society for Male Reproduction and Urology (SMRU) and the Society for the Study of Male Reproduction (SSMR). They recommend that the COVID-19 vaccine should not be withheld from men desiring fertility who meet criteria for vaccination. COVID-19 vaccines should be offered to men desiring fertility, like men not desiring fertility, when they meet criteria for vaccination.

These FAQs are offered to assist you as multiple organizations release their versions of the COVID-19 vaccine. Whether you are just beginning or continuing your fertility journey, it’s important to know the latest information on the vaccines and how they relate to you. We will update the below information as we receive updates from organizations and experts. The information below pertains to the mRNA vaccines of Pfizer-Biotech and Moderna.

### **1. Should the vaccine be given to pregnant women, lactating women or women planning a pregnancy?**

Yes, the vaccine should be offered to you if you are pregnant and meet the criteria from the CDC Advisory Committee on Immunization Practices (ACIP). This is also true for lactating women or those planning a pregnancy. According to research published March 23<sup>rd</sup> in the American Journal of Obstetrics and Gynecology, The Pfizer-Biotech and the Moderna Covid-19 vaccines are effective in pregnant and lactating women, who can pass protective antibodies to newborns.

Since the vaccines do not contain live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered. Given the known risks and severity of COVID-19 disease during pregnancy, the CDC and FCI physicians continue to support vaccination of pregnant women or women attempting pregnancy.

When you can access the vaccine will depend upon how you meet the ACIP criteria for recommended priority groups. Patients who conceive in the window between the first and second dose of the vaccine should be offered the second dose of the vaccine at the appropriate interval.

## **2. Is the vaccine safe for pregnant women and their unborn fetuses?**

The latest CDC updates state that data indicates that all three vaccines are safe for pregnant women. The American College of Obstetrics and Gynecology study above concurred.

It is known that these types of vaccines do not have live viruses, do not enter the cell nucleus, and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines should not be able to cause any genetic changes. The adenovirus vaccine is the same platform that has been used for other clinical vaccines in pregnant people.

The CDC has identified breakthrough cases of COVID-19 infection in vaccinated adults of both genders. This infection rate is .008%. The researchers found that 65% of breakthrough cases occurred in women, and 29% of all cases were asymptomatic.

## **3. What safety data are available about the vaccines and pregnancy?**

Despite SMFM's advocacy efforts, pregnant and lactating people have been excluded in many vaccine trials. However, in the study of 131 women who received either the Pfizer-Biontech or Moderna Covid-19 vaccine, the vaccine –induced antibody levels were equivalent in pregnant and lactating women, compared to non-pregnant women. The existing data indicates the safety of all three vaccines. As ongoing studies are concluded, additional safety data will become available in the coming months. The CDC is also currently enrolling pregnant individuals in a pregnancy registry.

To date, over 30,000 pregnant people have self-reported within the CDC v-safe program, which collects and reports outcomes including miscarriage and stillbirth, pregnancy complications, maternal ICU admission, adverse birth complications, neonatal death, infant hospitalizations, and birth defects. The reactogenicity and adverse events observed among pregnant people in v-safe do not indicate any concerning pregnancy outcomes, pregnancy complications, or neonatal outcomes compared with background data.

Reports to the Vaccine Adverse Event Reporting System (VAERS) from pregnant people (73%) include both pregnancy/neonatal-specific and nonpregnancy-specific adverse events (local and systemic reactions). Miscarriage was the most frequently reported pregnancy-specific adverse event reported to VAERS; however, the numbers are within expected background rates. Data from both v-safe and VAERS have not shown any patterns to indicate safety problems with the Pfizer and Moderna COVID-19 vaccines in pregnant people, and no unexpected pregnancy or infant outcomes have been reported. Safety monitoring in pregnant people is ongoing, and the Johnson and Johnson vaccine will be included in future vaccine safety surveillance activities.

While there had been studies showing that there was an increase in brain blood clots in the Johnson & Johnson vaccine (in all adults) further studies released April 15, indicated that the risk from these clots was greater from COVID 19 infections, than from the Johnson & Johnson vaccine. This prompted the CDC and FDA to approve resumption of the vaccine.

**4. Will FCI be administering the COVID-19 vaccine?**

We will not be administering the vaccines in our offices. Your primary care doctor may be administering the vaccine and the national program rollout will include administration of the vaccine at Walgreens, CVS, and other locations that have the capacity to store and determine eligibility.

**5. Can the vaccine cause an increased risk of infertility, pregnancy loss or congenital anomalies?**

Because COVID-19 mRNA vaccines (both Pfizer and Moderna) and the adenoviral vector vaccine (Johnson & Johnson) are not composed of a live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies. It should be noted that pregnant and lactating women were excluded from the initial phase III trials of these two vaccines, so specific safety data in these populations are not yet available and further studies are planned.

However, the mechanism of action of these vaccines and existing safety data provide reassurance regarding the safety of COVID-19 vaccines during pregnancy. The FDA EUA letter permits the vaccination of pregnant and breastfeeding individuals with a requirement that the company engage in post-authorization observational studies in pregnancy.

**6. What facts might a pregnant or lactating woman take into consideration when deciding whether to receive the vaccine?**

- The levels of virus activity in the community, which may change over time.
- Personal life and work circumstances that affect COVID-19 exposure.
- The efficacy of the vaccine, which is currently estimated at over 90% effective.
- The risks and potential severity of maternal disease from COVID-19, including the effects of disease on the fetus and newborn.

**7. Is it possible that the vaccine can affect fertility?**

Experts in reproductive health continue to recommend that the vaccine be available to pregnant individuals. There is no evidence that the vaccine can lead to loss of fertility. While fertility was not specifically studied in the clinical trials of the vaccine, no loss of fertility has been reported among trial participants or among the millions who have received the vaccines since their authorization, and no signs of infertility appeared in animal studies. Loss of fertility is scientifically unlikely. Dr. Jennifer Hirshfeld-Cytron addressed these issues in a recent [article](#) in the Chicago Tribune.

**8. Do pregnant women have a greater risk for serious infection and death if infected with COVID-19 compared to otherwise similar non-pregnant adults?**

Emerging studies suggest that **symptomatic** pregnant patients with COVID-19 are at increased risk of more severe illness compared with non-pregnant adults. On April 22, the Journal of the American Medical Association Pediatrics, reported that pregnant women infected with COVID-19 are at higher risk for adverse outcomes.

Further, pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness. Finally, Black and Hispanic individuals who are pregnant appear to have a disproportionately higher prevalence of COVID-19 infection and death.

It is of utmost importance that each woman communicates closely with her obstetrician to monitor and manage pregnancy during this time.

**9. What should a pregnant patient do if she develops a fever after immunization?**

While COVID-19 vaccination can cause fever in some patients, this risk should not be a concern when deciding whether to vaccinate a pregnant individual or a patient desiring pregnancy. While fever in pregnancy (particularly the 1st trimester) has been associated with an increased risk of neural tube defects, a recent study demonstrated the association no longer remained significant if the patient is taking over 400 mcg of folic acid daily.

Another large Danish cohort study did not demonstrate any increased risk of congenital anomalies in those who reported fever in the first trimester. Additionally, the most common symptom of COVID-19 infection itself is fever (83-99% of affected patients). Patients who experience fever following vaccination should take acetaminophen (Tylenol), which has been proven safe for use in pregnancy.

**10. What should a man who is interested in building a family do if he develops a fever after immunization?**

About 16% of men in the Pfizer/BioNtech COVID-19 vaccine clinical trial experienced fever *after the second dose*. Fevers can cause temporary declines in sperm production. Thus, if a man experiences fever as the result of the COVID-19 vaccine, he may experience a temporary decline in sperm production, but that would be similar to or less than if the individual experienced fever from developing COVID-19 or for other reasons.

**11. What if a patient becomes pregnant after the first dose of the COVID-19 vaccine is administered?**

The second dose should be administered as indicated. If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's V-SAFE program is encouraged.

**12. Is there any guidance on how long to wait after receiving the vaccine before I can become pregnant?**

Patients scheduled for elective surgery or outpatient procedures, including oocyte retrieval, embryo transfer, and intrauterine insemination, avoid COVID-19 vaccination at least three days prior and three days after their procedure. This recommendation is not because being vaccinated is unsafe, but rather because known side effects of the vaccine may impact intra-operative and post-surgical monitoring.

**13. If I have a high-risk pregnancy for other reasons is it better for me to get the vaccine? What do we know about the vaccine in women who are pregnant and have other medical problems?**

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Women with comorbidities like diabetes and hypertension may actually be at increased risk for severe consequences of COVID-19 infection and should be offered vaccination if they otherwise meet ACIP criteria.

**14. If I have allergies to medications, can I still get the vaccine?**

Reactions to vaccines are rare, however the [CDC has updated guidelines](#) which state that anyone who has previously suffered an allergic reaction of any severity to any ingredient of the Moderna, Pfizer, or Johnson & Johnson vaccines, should only be vaccinated after clearance from their primary care doctor. The vaccines contain polyethylene glycol, which in people who have sensitivity to polysorbate, may cause a reaction.